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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,580	01/25/2007	David Grenville Holmes	33485A	5095

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,580	HOLMES, DAVID GRENVILLE	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I , claim(s) 1-6, 13, and 15 are drawn to a combination comprising a DPP IV inhibitor or a pharmaceutically acceptable salt thereof, and at least one therapeutic agent selected from the group consisting of i) an antiobesity agent or a pharmaceutically acceptable salt thereof, ii) an appetite regulating agent or a pharmaceutically acceptable salt thereof.

Group II, claim(s) 7, 10-12, and 16 are drawn to method for the prevention of, delay of progression of, treatment of a disease or condition selected from the group consisting of
(a) type 2 diabetes mellitus and related diseases, disorders or conditions;
(b) insulin resistance and syndrome X, obesity and related diseases, disorders or conditions; (c) hypertension including hypertension in the elderly, familial dyslipidemic hypertension, and isolated systolic hypertension (ISH); increased collagen formation, fibrosis, and remodeling following hypertension; erectile dysfunction, impaired vascular compliance, stroke; all these diseases or conditions associated with or without hypertension;
(d) congestive heart failure, left ventricular hypertrophy, survival post myocardial infarction (MI), coronary artery diseases, atherosclerosis, angina pectoris, thrombosis;
(e) renal failure, especially chronic renal failure, glomerulosclerosis, nephropathy;
(f) hypothyroidism;
(g) endothelial dysfunction with or without hypertension;
(h) hyperlipidemia, hyperlipoproteinemia, hypertryglyceridemia, and hypercholesterolemia; (i) macular degeneration, cataract, glaucoma;
(j) skin and connective tissue disorders, and
(k) restenosis after percutaneous transluminal angioplasty, and restenosis after coronary artery bypass surgery; peripheral vascular disease; comprising administering to a warm-blooded animal, including man, in need thereof a jointly effective amount of a combination of a DPP IV inhibitor or a pharmaceutically acceptable salt thereof with at least one therapeutic agent selected from the group consisting of
(i)
an antiobesity agent or a pharmaceutically acceptable salt thereof,
(ii)

an appetite regulating agent or a pharmaceutically acceptable salt thereofl.
(iii)
a renin inhibitor or a pharmaceutically acceptable salt thereof
.

The inventions listed as Groups I – II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is drawn to a combination while Group II is drawn to a method for preventing and/or delaying. In other words, the product combination of Group I could be used in a different method other than claimed. Likewise, the method as claimed could be used for a materially different product. An example of the former would be thus:

The present invention provides a therapeutic agent for treatment of diabetes and hyperlipemia, especially a therapeutic agent for diabetes mellitus, which comprises as the active ingredient a neurotrophic factor such as BDNF (brain-derived neurotrophic factor), ligands of trkB or trkC receptors, NGF, NT-3, NT-4/5, CNTF, GDNF, HGF, etc. Different from conventional oral hypoglycemic agents being mainly used in the treatment of type II diabetes mellitus, the agent of the present invention exhibit blood lipid regulating effects and body fat accumulation regulating effects, in addition to the blood glucose regulating effects. Thus, the agent of the present invention is novel, and can reduce the risk factors in diabetes accompanied by hyperlipemia or obesity, without using any other agent (Kishino et al. USPN 6,391,312 B1).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicants' are required to elect one species from (A) to (D).

(A) The election of one, exact, and specific combination, i.e., DPP IV inhibitor, antiobesity drug, and an appetite regulating agent as a unit combination or the pharmaceutical salts thereof in a unit combination. If there will be a combination disclosing a salt of an active agent with agents that are not the salt derivative, this distinction must be clearly pointed out in the election.

(B) The election of one, exact, and specific DPP IV inhibitor

(C) The election of one, exact, and specific anti-obesity agent or appetite regulating agent

(D) The election of one, exact, and specific disease or condition

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim1, 4, 5, 9 , 10, 12-15 discloses DPP IV species.
Claims 6 and 11 disclose an anti-obesity or appetite regulating agent.
Claim 7 discloses disease and conditions of said invention

The following claim(s) are generic: 1-16.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species of diseases are distinct from a species of a pharmaceutical composition classified as an inhibitor. The said inhibitor, a pharmaceutical composition is indicated to be administered in order to treat a species of disease. For the same reasons just explained, glucocorticoid species and alkylating agent species are distinct from any species of diseases. Likewise, glucocorticoid species are distinct from alkylating agents via classification, mechanisms of action, indication of treatment, biopharmaceutics, etc. These agents are both and each distinct from inhibitors of Type 4 cyclic adenosine monophosphate phosphodiesterases as indicated.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or

access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/

Primary Examiner, Art Unit 1617

TEB